REMARKS

By this amendment, Applicants have made minor amendments to claims 54 and 70 and have added new claim 91. Claims 57, 67, 71-81, and 88-90 stand withdrawn from consideration and thus claims 46-56, 58-66, 68-70, 82-87, and 91 are currently under examination in the present application. For the reasons set forth below, Applicants submit that the present amendments and arguments place this application in condition for immediate allowance.

As an initial matter, in the Office Action of September 2, 2008, the Examiner rejected claims 54 and 70 under 35 U.S.C. 112, second paragraph as being indefinite. In particular, the Examiner asserted that the limitation "p7 protein" in claim 54 lacked antecedent basis and that it was not clear whether the preferred embodiment included in claim 70 was a claim limitation. Without addressing the merits of these rejections, these rejections have now been rendered moot by virtue of the present amendments and, accordingly, Applicants submit that the Examiner's rejections are respectfully traversed and should be withdrawn.

Specifically, with regard to the Examiner's assertion that the limitation "p7 protein" lacks antecedent basis in claim 54, Applicants have now amended claim 54 to properly depend from claim 53 in accordance with the Examiner's suggestion. As such, Applicants respectfully submit that there is sufficient antecedent basis for the limitation "p7 protein" in claim 54 as claim 53 refers to a "native p7 protein."

With regard to the Examiner's assertion that it was unclear whether the preferred embodiment included in claim 70 is a claim limitation, by the present

amendments, the phrase "preferably a hepacivirus core protein" has now been removed from claim 70. In accordance with the Examiner's suggestions, this embodiment has now been included in new claim 91, which depends from claim 70. In light of the foregoing, Applicants thus respectfully submit that the claims of the present application fully comply with the requirements of 35 U.S.C. 112, second paragraph and that the Examiner's rejections should be withdrawn.

In the Office Action, the Examiner then rejected claims 46-56, 58-66, 68-70, and 82-87 under 35 U.S.C. §103(a) as being unpatentable over Marasco, et al. (WO 00/55335) in view of both Lechmann, et al. (Hepatology, 2001, 34: 417-423) and Ray, et al. (FEMS Microbiology Letters, 2001, 202: 149-156). In particular, although the Examiner acknowledged that Marasco does not teach or suggest an HCV polyprotein, the Examiner asserted that it would have been obvious to modify the methods of Marasco by using the polyprotein of Lechmann to obtain infectious HCV-like particles. Further, the Examiner asserted that by including an HCV core protein, a signal sequence would have necessarily been included because Ray teaches that the signal sequence is required for the proper targeting of the polyprotein to the host cell endoplasmic reticulum. For the reasons set forth below, Applicants respectfully traverse the Examiner's rejection and request that it be withdrawn.

In contrast to the present application, Marasco describes a system of vectors that are useful for gene delivery and comprise a first vector that includes a lentiviral gag gene encoding a lentiviral gag protein, a second vector that includes an env gene encoding a functional envelope protein, a lentiviral pol gene encoding a lentiviral pol

protein, and a packaging vector that contains a nucleic acid encoding a desired molecule. Marasco specifies that the env gene may be heterologous and may be from a virus of the hepatitis or the flavivirus group. However, Marasco only cites the HAV, HBV, and HEV viruses as sources of an env gene, and does not teach or suggest that HCV could be utilized. In this regard, the Examiner has thus asserted that it would have been obvious to modify the method described in Marasco with the polyproteins described in Lechmann to obtain infectious HCV-like particles.

Contrary to the Examiner's assertions, however, the information disclosed in Marasco and Lechmann would not have led one of ordinary skill in the art to utilize HCV proteins to obtain infectious HCV-like particles, as described in the present application. Marasco describes numerous associations between cell lines and particular virus types, including HAV, HBV, HEV, and flavivirus. However, hepacivirus and HCV are expressly excluded from the exhaustive list of viruses described by Marasco, which would lead one of ordinary skill in the art to conclude that the methods described in Marasco would not be applicable to HCV or hepaciviruses. Although all hepatitis viruses infect hepatocytes and cause hepatitis, each hepatitis virus is distinct genetically and clinically. As such, the use of the other hepatitis viruses, namely HAV, HBV, and HEV, in the methods of Marasco does not teach or in any way suggest that HCV could also be used in the methods described by Marasco.

Furthermore, Lechmann provides no teaching or suggestion that a polyprotein comprising HCV core, E1, and E2 proteins could be used in a method, such as the one

described in Marasco, to obtain infectious HCV-like particles. Indeed, Lechmann does not teach or suggest that the HCV-like particles described in that reference are immunogenic, much less teach or suggest that these pseudoparticles are infectious, and thus capable of initiating an infection and/or cell entry. Ray adds nothing further in this regard and was merely cited by the Examiner for its teachings regarding the signal sequence of the HCV core protein.

Accordingly, Applicants respectfully submit that the present invention is not rendered obvious by the Marasco, Lechmann, or Ray references, and that the claims of the present application relating to a method for producing infectious hepacivirus-like particles are clearly patentable over those references. Applicants thus submit that the Examiner's rejections on the basis of those references is respectfully traversed and should be withdrawn.

Finally, in the Office Action of September 2, 2008, the Examiner provisionally rejected claims 46-56, 58-66, 68-70, and 82-87 on the grounds of non-statutory obviousness-type double patenting as being unpatentable over U.S. Application No. 10/547,750 in view of Lechmann, et al. (Hepatology, 2001, 34: 417-423). Without addressing the merits of this rejection, Applicants are submitting herewith a terminal disclaimer under 37 C.F.R. §1.321(c). As such, Applicants respectfully submit that the double patenting rejection has become moot and should be withdrawn.

In light of the amendments and arguments provided herewith, Applicants submit that the present application overcomes all prior rejections and objections, and has been placed in condition for immediate allowance. Such action is respectfully requested.

Respectfully submitted,

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